

REMARKS

Reconsideration is requested.

Claim 40 has been added and is based on the original claim 11 as well as the disclosure, for example, in Example 2.5 of the present application as well as Example 12 of the present application. No new matter has been added. Claims 8-10, 13, 14, 17-33 and 38-40 are pending. The applicants acknowledge, with appreciation, the allowance of claims 9, 10, 13, 14 and 18-29. Claims 8, 17, 30-33, 38 and 39 have been rejected under Section 112, first paragraph. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

The Examiner interview with the undersigned on September 7, 2001, is acknowledged, with appreciation. During the interview, the undersigned discussed with the Examiner the outstanding Section 112, first paragraph, rejection of claims 8, 17, 30-33 and 38-39, in relation to the Guidelines for Examination of Patent Applications Under 35 USC 112, ¶1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, pages 1099-1111 (copy attached). The undersigned believes the Examiner directed the undersigned's attention to Examples 6-8 of the "Revised Interim Written Description Guidelines Training Materials" (copy attached) as a basis for maintaining the Section 112, first paragraph, rejection. The undersigned believes the attached "Revised Interim Written Description Guidelines Training Materials" were prepared to accompany the "Revised Interim Guidelines for Examination of Patent Applications under the 35 USC 112, ¶1 'Written Description' Requirement" published in the Federal Register at 64 F.R. 71427, December 21, 1999,



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however the Examiner is requested to advise if otherwise. The attached "Revised Interim Written Description Guidelines Training Materials" do not contain a publication date.

The applicants have again reviewed the Training Materials received from the Examiner and they continue to believe that the cited Examples (i.e., 6-8) referred to by the Examiner are not relevant to the pending claims. Specifically, Example 6 involves a cDNA fragment the activity of which is untested but based purely on homology. The claim is specifically to the entire gene. The comments of Example 6 should not be seen as applicable to the present case wherein several full length cDNAs with proven activity are disclosed (see, Example 13) and claimed in a manner which does not specifically recite a gene.

Example 7 of the Training Materials involves a partial cDNA (EST). This Example is not relevant to the pending claims for reasons similar to those noted above with regard to Example 6.

Example 8 provides a fact pattern wherein the written description requirement is satisfied.

Even if these Training Materials supported the Examiner's position, the 2001 Guidelines clearly supersede the Revised Interim 1999 Guidelines (see, second sentence of the Summary on page 1099-2<sup>nd</sup> column) i.e., if there is any conflict, then these later guidelines (copy attached) should clearly be applied.

The applicants previously referred to the "comments" section preceding the 2001 Guidelines because these expressly state in comment 14 that in relation the present

situation *viz.* "class of nucleotides encoding a polypeptide" [see claim 8] the earlier Guidelines have indeed been superseded (and new training materials will be issued). The Examiner is requested to provide a copy of the same.

It must be stressed that neither the wording of claim 8, nor the reference in the description at page 5, last line, amount to a *specific* claim to the genomic sequence (cf. Example 6 above). Although such sequences may be encompassed within the genus, the Guidelines (see, page 1106, column 3, 15<sup>th</sup> line from bottom onwards, and particularly footnote 57) expressly make the point that:

"...Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.<sup>57</sup>"

However it seems to be precisely on the basis that the claim to the genus has been impugned i.e., that because the applicants do not provide specific "*individual support*" for the genomic sequence, the applicants allegedly have not provided support for the *genus*.

The Examiner notes that the Guidelines seem to permit the "encoding" claims on the basis of degeneracy and that it does not address the genomic /cDNA issue. However, if the Examiner's position on such "encoding" claims was correct, it rather begs the question of why it would not be set out in the Guidelines when such "encoding" claims are discussed and (in principal) approved under Section 112, first paragraph. Its very absence supports the applicants arguments that the Examiner is misinterpreting the Section 112, first paragraph, requirement.

Claims 8, 17, 30-33 and 38-39 are submitted to be supported by an adequate written description.

With regard to new claim 40, the applicants note that the Examiner had previously relied on *Ex parte Maizel*, 27 USPQ2d 1662 (see, page 6 of Office Action dated July 2, 1997) in rejecting claim 11. However it appears from the Examiner's description of *Maizel* that the claims at issue in *Maizel* covered any nucleic acid encoding a protein having a given activity i.e., a purely functional claim. The present claim 40 is directed to nucleic acids which are closely related to the sequence provided by the present inventors, and which (by definition) could be obtained by one ordinarily skilled in the art using that sequence, under prescribed conditions. Thus, claim 40 is submitted to be supported by an enabling disclosure.

Regarding "written description" the attention of the Examiner is drawn to Example 9 of the Interim Guidelines Training Materials. Unlike the situation for claim 8 above, the applicants have no reason to believe that this aspect of the Training Materials have been superseded.

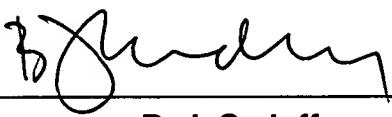
As for the previously cited art, the applicants submit claim 40 is patentable over the same.

In view of the above and attached, the claims are submitted to be in condition for allowance and a Notice to that effect is requested.

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Respectfully submitted,

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